K130456

APR 0 8 2014

510(k) SUMMARY

Submitter's Name, address, telephone number, a contact person and date the summary was prepared:

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Date 510(k) summary prepared:	March 8, 2014

Name of the device, including the trade or proprietary name if applicable, the common or usual name and the classification name, if known:

Proprietary Name:	Wunder Pregnancy Test
Common or Usual Name:	Chorionic gonadotropin test system
Classification Name:	Enzyme immunoassay, hCG
Classification Code:	21 CFR 862.1155, Class II
Product Code:	JHI

Description of the Device:

Wunder Pregnancy Test is a single-use qualitative immunochromatic lateral flow device intended to detect human chorionic gonadotropin (hCG) in urine to help in the early detection of pregnancy. The device is visually read and intended for prescription use.

Wunder Pregnancy Test is provided in a cassette format. A pipette is included for use with the device. The operator utilizes the included pipette to collect a sample of urine specimen to be tested from a sample cup. The operator then dispenses the urine specimen into the round sample well of the device. An absorbent, nitrocellulose membrane strip is incorporated in the sample well into the rectangular window where the results are read. In the results window, there are two band regions on the membrane strip, a test band and a control band. The test band region is pre-coated with Goat anti-α hCG antibodies. Goat anti-β monoclonal antibodies are placed on the membrane between the test band and the sample well. During the test, the urine sample is allowed to migrate upward and hydrate the anti-β monoclonal antibodies. The mixture then migrates along the membrane by capillary action to the immobilized Goat anti-α hCG antibodies in the test band region.

In the presence of hCG in the urine, the anti-β monoclonal antibodies bind with the hCG β unit antigen and moves with the sample urine fluid by capillary action along the membrane. As the solution reaches the test band, the anti-β antibody hCG β-unit antigen complex becomes linked to the pre-coated Goat anti-α hCG antibodies to form a visible precipitate that can be seen as a color line at the test band. Therefore, the formation of a visible color line on the test band region indicates the urine sample has tested positive for hCG.

In the absence of hCG in the urine, the anti-β monoclonal antibodies bypass the pre-coated Goat anti-α hCG antibodies in the test region without forming a visible precipitate. As a result, the absence of a visible color line in the test band region indicates the urine sample tested is negative for hCG.

The distal control band region is pre-coated with Goat anti Mouse IgG. If there is sufficient urine volume, the anti-β antibodies will migrate by capillary action to the control region. The anti-β antibodies will bind with the Goat anti Mouse IgG and precipitate to form a color line. This antigen-antibody reaction at the control line ensures that the test is performed properly and should always be seen as a visible line during testing. The presence of this color band in the control region serves as verification that sufficient urine volume has been added and that proper flow was obtained. In conclusion, a valid positive urine sample produces two distinct color bands. A valid negative sample produces only one color band in the control zone.

Statement of the Intended Use:

Wunder Pregnancy Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in human urine. The device is visually read as an aid for the early detection of pregnancy and intended for in vitro single use. This test is intended for prescription use including at point-of-care sites.

Summary of the technological characteristics of the device compared to the predicate devices

Performance of the Wunder Pregnancy Test was compared to dBest Pregnancy Test (510k # k061257). Both tests are immunochromatic, lateral flow assays for the qualitative detection of hCG in urine. Both tests are intended to provide preliminary pregnancy test results.

Similarities		
Features	Device	Predicate
Name	Wunder Pregnancy Test	dBest Pregnancy Test
Intended use	For detection of hCG as an aid in the early detection of pregnancy	Identical

Mechanism of action	Immunochromatographic lateral flow assay with visual, qualitative screening result	Identical
Time to result	5 minutes	Identical
Reusability	No, one-time use	Identical
Use	Prescription	Prescription and OTC

Differences		
Features	Device	Predicate
Name	*Wunder Pregnancy Test*	dBest Pregnancy Test
Product design	Cassette	Dipstick
Size	Smaller size (2.72" x 0.75" x 0.18")	Larger size (5.25" x 0.6" x 0.4")
Physical design	Plastic casing with round "sample well" for urine collection with a provided pipette	Plastic casing with absorbent tip in a dipstick case
Storage temperature	18-28°C (64-82°F)	4-30°C (40-86°F)

Summary of Performance Testing:

1. Method Comparison Study
   100 female patient urine samples were collected and tested at three point of care locations and compared to the predicate device. Patients included women with suspected pregnancy and with possible pregnancy gestational age up to 10 weeks. The results of the comparison with the predicate device were as follows:

		Commercially Available Pregnancy Test		
		+	-	Total
Wunder Pregnancy Test	+	69	0	69
	-	0	31	31
	Total	69	31	100

2. Sensitivity
   To evaluate sensitivity, urine samples from nonpregnant subjects were spiked with hCG to concentrations of 0, 12.5, 25, 37.5, 50 and 100 mIU/mL and tested at three point of care locations. The study establishes the cut-off value for the Wunder Test Pregnancy Test at 25 mIU/mL.

hCG levels mIU/mL	Total No. Tested	% Agreement	Results (+/-)
0	60	100	0/60
12.5	60	100	0/60
20	60	51	31/29
25	60	100	60/0
37.5	60	100	60/0
50	60	100	60/0
100	60	100	60/0

3. Specificity
No interference was observed in the testing of hCG using the Wunder Pregnancy Test when the following concentrations of hormones were added to urine samples containing 0 and 25 mIU/mL hCG: hLH 500 mIU/mL, hFSH 1000mIU/mL, and hTSH, 1000 µIU/mL.

4. Interference Data
   a. Interference effect of the hCG beta-core fragment
   hCG beta core fragment was tested at increasing concentrations and found to produce a false negative test result at a concentration in excess of 250,000 pmol/L. Correct results were obtained in the presence of hCG beta-core fragment at concentration equal to or less than 250,000 pmol/L.

   b. Hook effect
   In evaluating for high dose hook effect, negative urine specimens were spiked with high hCG concentrations and found to produce a false negative test result at a concentration in excess of 1,000,000 mIU/mL. Correct results were obtained when testing urine samples with hCG concentrations equal to 1,000,000 mIU/mL with this device.

   c. Interference effects of endogenous and exogenous substances
   The following substances were found not to interfere with the Wunder Pregnancy Test.

Acetaminophen	20 mg/dL
Acetylsalicylic acid	20 mg/dL
Atropine	20 mg/dL
L-Ascorbic acid	20 mg/dL
Caffeine	20 mg/dL
Salicylic acid	20 mg/dL
Ampicillin	20 mg/dL
Glucose	2 mg/dL
Hemoglobin	1000 mg/dL
Benzoylecgonine	10 mg/dL
Albumin	100 mg/dL
Bilirubin	2 mg/dL
Ethanol	1%

   Urine specific gravity (1.000-1.030) and urine pH (3-9) do not interfere with the test results of the Wunder Test Pregnancy Test.

5. Conclusions
   Study data support the determination of substantial equivalence of the Wunder Pregnancy Test to the predicate device. Comparison testing of 100 clinical samples demonstrate a >99% agreement of the Wunder Pregnancy Test with the predicate device. The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 8, 2014

JAMES NGUYEN, M.D.
2231 FORTUNE DR, STE D
SAN JOSE CA 95131

Re: K130456
Trade/Device Name: Wunder Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: II
Product Code: JHI
Dated: February 20, 2014
Received: February 24, 2014

Dear Dr. Nguyen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer

Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k130456

Device Name
Wunder Pregnancy Test

Indications for Use *(Describe)*
Wunder Pregnancy Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in human urine. The device is visually read as an aid for the early detection of pregnancy and intended for in vitro single use. This test is for prescription use including at point-of-care sites.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Avis T. Danishefsky -S

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